REMARKS

Reconsideration of the captioned application as amended herewith is respectfully requested.

This amendment is filed concurrently with a Petition for a **one (1) month** Extension of Time to File a Response, which will extend the period of response to the Office Action from 29 December 2006 to 29 January 2007.

The Office Action:

a) objected to the Specification as allegedly failing to provide proper antecedent basis for the claimed subject matter in claims 16, 24 – 27, 29, and 30;

b) rejected claims 14, 16 – 19, 21, 22, 24 – 27, 29, and 30 under 35 USC §112, Second Paragraph as allegedly being incomplete, and further rejected claim 24 as under 35 USC §112, Second Paragraph, as allegedly being indefinite;

c) rejected claims 2 – 6, 8, 9, 11, 13, 14, 16 – 19, 21, 22, 24 – 27, 29-33, 35, 36, and 73 under 35 USC §103(a) by United States Patent No. 5,789,014 to Maruyama, et al. ("Maruyama") in view of United States Patent No. 3,431,138 to Zingerman et al., ("Zingerman"); United States Patent No. 6,139,865 to Friend, et al. ("Friend"), CA 2068366 ("Abstract"), and United States Patent No. 5,958,458 to Norling, et al. ("Norling").

Claim 14 was clarified to be directed to an "oral dosage form" that is further comprised of "at least one excipient." Support for this amendment may be found in the Specification as originally filed at, for example, page 1, lines 10 – 13 and 24 - 26, page 7, lines 18 – 21, and page 11, lines 1 – 5, and as such this amendment does not introduce new matter into the application. Claims 16, 17, 19, 21, 22, and 24 were similarly amended.

Claim 18 was clarified to reflect that the "oral dosage form" may be "a lozenge, a chewable tablet, [or] a rapidly dissolving tablet." Support for this amendment may be found in the Specification as originally filed at, for example, page 1, lines 6 - 12 and lines 24 - 27, and as such this amendment does not introduce new matter into the application. Applicants also wish to point out that claims of this format are commonly found in pharmaceutical patents. See e.g., USP 7,125,564, claim 11; and USP 7,138,137, claim 13 (copies attached).

New claim 74 was added to further claim the present invention. Support for this claim may be found in the Specification as originally filed at, for example, page 1, lines 6 – 17, 24 – 27, page 7, lines 18 – 21, page 8, lines 13 – 15, and page 11, lines 1 – 5, and as such this

amendment does not introduce new matter into the application. Claim 74 depends from claim 18, which as discussed below, is patentable over the prior art.

New claims 75 and 76 were added to further claim the present invention. Support for this claim may be found in the Specification as originally filed at, for example, page 1, lines 34 – 36; page 2, lines 8 – 14; page 3, lines 37 – 39; and page 4 lines 29 – 32, and as such this amendment does not introduce new matter into the application. Claims 75 and 76 relate to oral dosage forms comprising particles recited in the prior claims, which as discussed below, are patentable over the prior art.

Claims 1, 7, 10, 12, 15, 20, 23, 15 - 30, 34, and 37 - 72 were cancelled. New claims 74 – 76 were added. Claims 2 – 6, 8 – 9, 11, 13 -14, 16 – 19, 21- 22, 24, 31 - 33, 35 -36, 73, and 74 - 76 remain pending in this application after entry of this amendment.

The Objection to the Specification for Allegedly Failing to Provide Antecedent Basis for Claims 16, 24 – 27, 29, and 30 Should Be Withdrawn

The Specification was objected to for allegedly failing to provide proper antecedent basis for the claimed subject matter in claims 16, 24 – 27, 29, and 30. Applicants respectfully disagree for the reasons that follow.

In view of the cancellation of claims 25 - 27, 29, and 30, Applicants respectfully submit that the objection to these claims has been overcome and should be withdrawn.

The Specification was amended on pages 3 – 4 to include that the first coating layer may be "substantially free of plasticizer." Support for this language may be found in the Specification as original filed in claims 16 and 24, and as such this amendment does not introduce new matter into the application. In view of this amendment to the Specification, Applicants respectfully submit that the objection to the Specification for allegedly not having support for claims 16 and 24 in the Specification has been overcome and should be withdrawn.

According to the Office Action, claims "24 – 27, 29, 30 claim a rapidly disintegrating tablet," but the Specification allegedly does not disclose rapidly disintegrating tablets. In view of the disclosure in Applicants' Specification as originally filed at, for example, page 1, lines 6 – 12 and 24 - 27, Applicants respectfully submit that the objection to Specification for allegedly failing to provide proper antecedent basis for claims 24 – 27, 29 and 30 has been overcome and should be withdrawn.

The Rejection of Claims 14, 16 – 19, 21, 22, 24 – 27, 29, and 30 under 35 USC §112, Second Paragraph, Should Be Withdrawn

Claims 14, 16 – 19, 21, 22, 24 – 27, 29, and 30 stand rejected under 35 USC §112, second paragraph. Applicants disagree for the reasons that follow.

In view of the cancellation of claims 25 - 27, 29, and 30, Applicants respectfully submit that the rejection to these claims has been overcome and should be withdrawn.

The remaining pending claims, i.e., claims 14, 16 – 19, 21, 22, and 24, stand rejected for allegedly "being incomplete for omitting essential structural cooperative relationships of elements." Applicants respectfully disagree. Claim 14, as amended, is directed to an "oral dosage form" comprised of a) "the particles of claim 8" and b) "at least one excipient." Applicants respectfully submit that the claim contains all elements essential to describing one embodiment of the present invention. Applicants further respectfully submit that this type of claim is commonly found in the pharmaceutical patents. See, e.g., USP 5,958,453, claims 8 and 16; USP 4,965,072, claim 5; and USP 7,125,564, claim 1 and 11 (copies attached). Therefore, Applicants respectfully submit that this rejection to claims 14, 16 – 19, 21, 22, and 24 under 35 USC §112, second paragraph, as allegedly omitting essential structural cooperative relationship of elements, has been overcome and should be withdrawn.

In view of the deletion of the terms, "or the second coating layer," Applicants respectfully submit that the rejection of claim 24 under 35 USC §112, second paragraph, as allegedly being indefinite has been overcome and should be withdrawn.

The Rejection of Claims 2 – 6, 9, 11, 13, 14, 16 – 19, 21, 22, 24 – 27, 29-33, 35, 36, and 73 under 35 USC §103(a) as Unpatentable Over Maruyama in view of Zingerman, Friend, Abstract, and Norling Should Be Withdrawn

Claims 2 – 6, 9, 11, 13, 14, 16 – 19, 21, 22, 24 – 27, 29-33, 35, 36, and 73 stand rejected under 35 USC §103(a) by Maruyama in view of Zingerman, Friend, Abstract, and Norling. Applicants respectfully disagree for the reasons that follow.

In view of the cancellation of claims 25 - 27, 29, and 30, Applicants respectfully submit that the rejection to these claims has been overcome and should be withdrawn.

According to the Office Action, the

> prior art discloses a solid preparation containing a first coat … and a second coat containing a mixture of HPMC and PEG. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose using the ratio of HPMC to PEG of about 80:20 to about 20:80. However, the prior art [allegedly] amply suggest the same….

(emphasis added) Applicants respectfully disagree that, for example, the cited prior art discloses the use of "a second coat containing a mixture of HPMC and PEG."

> Maruyama discloses that its coated cores
>
> may be further coated with a granule adhesion preventing agent, which is a mixture of one or more types chosen from among metal salts of inorganic or organic acids …, aqueous polymers … and waxes ….

Maruyama, Column 6, lines 20 – 27 (emphasis added). Maruyama then discloses that examples of "metal salts of inorganic or organic acids includ[e] talc, Carplex (SiO_2), magnesium stearate and calcium stearate," and examples of "aqueous polymers includ[e] hydroxypropylmethyl cellulose, hydroxypropyl cellulose and polyethylene glycol." Maruyama further discloses that examples of "waxes includ[e] carnauba wax, bees wax and paraffin." See Maruyama, Column 6, lines 20 – 27.

Applicants respectfully submit that Maruyama fails to specifically disclose or suggest "a second coat containing a mixture of HPMC and PEG" as proposed in the Office Action. First, Maruyama broadly discloses the use of a granule adhesion preventing agent coating that may be "a mixture of one or more types [of] metal salts of inorganic or organic acids[,] aqueous polymers [,] and waxes." Maruyama, Column 6, lines 20 – 27 (emphasis added.) Then, Maruyama provides about ten examples of species within these three genus types of granule adhesion preventing agents. However, Maruyama fails to specifically disclose or suggest the use of a coating comprised of only "aqueous polymers." Maruyama also fails to specifically disclose or suggest the selection of two particular "aqueous polymers," let alone the selection of specifically hydroxypropylmethyl cellulose and polyethylene glycol. Maruyama further fails to offer any justification for using a combination of any of these ingredients at a ratio of "about 20:80 to about 80:20." Furthermore, Maruyama further fails to disclose or suggest oral dosage forms which are "chewable tablets" or "rapidly dissolving tablets" as claimed herein.

As is well founded in the case law, an obviousness determination cannot be based on a "hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. There must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor. When the patented invention is made by combining known components to achieve a new system, the prior art must provide a suggestion or motivation to make such a combination." See Crown Operations Intl. Ltd. v. Solutia, 289 F.3d 1367 (Fed. Cir. 2002).

Applicants respectfully submit that one of ordinary skill who reviewed the Maruyama reference would not have been motivated to specifically select a mixture of polymers within the aqueous polymer genus of Maruyama's granule adhesion preventing agents. Moreover, Applicants further respectfully submit that one of ordinary skill would not have been motivated to specifically select the combination of hydroxypropylmethyl cellulose and polyethylene glycol out of the many species of granule adhesion preventing agents listed and suggested therein, let alone to specifically select such agents at a ratio of "about 20:80 to about 80:20" as claimed herein. Especially given the fact that the components suitable for the second coating layer in Maruyama were used for a completely different purpose (i.e., as "granule adhesion preventing agent[s]") and not for texture masking of particles as claimed herein, Applicants respectfully maintain that one skilled in the art could not arrive at the present invention without improperly relying upon Applicants' own Specification in hindsight.

In sum, Applicants respectfully submit that there was not a teaching or suggestion in the prior art that: (1) the claimed composition could or should be prepared; or (2) the reasonable expectation of success. See In re Fine, 837 F.2d 1071 (USPTO has burden of establishing a prima facie case of obviousness, which can only be satisfied by showing some objective teaching in the prior art or knowledge that was generally available to one of ordinary skill in the art that would lead that person to the present invention). Applicants respectfully submit that the Office Action has failed to point to anything in the cited references, either alone or in combination, that would suggest or teach the use of a second coating layer comprised of the specific combination of anti-grit agents and film forming polymers at the ratio claimed in Applicants' claimed invention.

Applicants further respectfully submit that the additional cited art fails to provide any further suggestion or motivation that would teach the use of a second coating layer comprised of the specific combination of anti-grit agents and film forming polymers at the ratio claimed in Applicants' claimed invention.

According to the Office Action, Zingerman "discloses that addition of polyethylene glycol to a cellulosic coating composition improves the flexibility and smoothness of the finished coating layer." However, Zingerman is directed to coatings for tablets, and not to coatings for granules as claimed herein. Thus, there is no disclosure or suggestion in Zingerman that the coatings suitable for tablets would also be suitable for coating particles as claimed herein.

Moreover, Zingerman is directed to the use of polyethylene glycol on coating compositions for purposes of, for example, improving the "smoothness of the finished coating layer" on a tablet. Thus, not only does Zingerman fail to disclose or suggest the use of its coatings on particles (as opposed to solid tablets), but it also fails to disclose or suggest how its coatings will perform as texture masking agents for particles during ingestion. Beneficially, Zingerman describes that its coated, smooth tablets can have printing applied thereto without damage to the coating. See Zingerman, column 3, lines 37 – 41. More specifically, smoothness is a quality that describes, for example, the appearance of a coated tablet. By contrast, texture masking agents typically are able to hydrate particles sufficiently such that they can comfortably pass by the tongue during ingestion without the user's incurring a gritty sensation. Applicants respectfully submit that there is no disclosure or suggestion in Zingerman as to whether its coatings possess these texture masking qualities or would be suitable for texture masking purposes.

In addition, Zingerman further fails to disclose or suggest: (a) the use of a "first coating layer comprised of a taste masking agent" on a particle; and (b) the use of a "compressible carbohydrate" in a dosage form comprised of the coated particles as claimed in claim 74.

In sum, Applicants respectfully submit that one skilled in the art, who was looking for a means to effectively mask the texture of drug particles during ingestion, especially after the other excipients in the dosage form matrix have dissolved, would not likely look to a reference that was directed to improving the smoothness of a coating layer surface on a solid core tablet as taught in Zingerman.

According to the Office Action,

> the affidavit (10/21/2005) is [allegedly] not sufficient to overcome the rejection herein.... The prior art, however, discloses that polyethylene glycol is added to increase flexibility and smoothness of the finished coating. As such, it is not unexpected that reducing the amount of PEG would result in the coating being less smooth. As such, the affidavit does not show unexpected results.

As set forth above, Applicants respectfully submit that the smoothness of a coated tablet is a completely different property than its texture masking effectiveness for coated particles. More specifically, a coating that may effectively improve the smoothness of a substrate surface would not necessarily also have effective texture masking agent properties, such as, e.g., sufficient hydration properties that would enable coated particle substrates to comfortably pass by the tongue during ingestion without the user's incurring a gritty sensation. Contrary to the suggestion in the Office Action, Applicants respectfully submit that one skilled in the art who was looking to texture mask a particle would not look to a reference like Zingerman, which discloses the addition of polyethylene glycol to a coating for a tablet (not a particle) in order to improve the smoothness of its surface. *Assuming arguendo* that a reference like Zingerman were considered, Applicants respectfully submit that one skilled in the art, who was looking for an effective texture masking coating, would still not be motivated to include polyethylene glycol with a film forming polymer just because of the polyethylene glycol's ability to increase the smoothness of a tablet coating.

The other cited art also fails to disclose or suggest the need or the method for modifying the secondary coating of Maruyama, let alone the need or the method for so modifying the "granule adhesion preventing agent" in order to modify it into a coating like the "second coating layer comprised of i) a film forming polymer; and ii) an anti-grit agent, wherein the weight ratio of film forming polymer to anti-grit agent in the second coating layer is in the range of about 20:80 to about 80:20 " (emphasis added) as claimed herein. Rather, Friend and the Abstract only exemplify certain components suitable for tastemasking agents, such as those suitable for Applicants "first coating layer comprised of a taste masking agent." (emphasis added) The Office Action further found that Norling teaches ingredients for "mask[ing] the bad tasting active substances," and not coatings for masking texture as claimed.

Therefore, in view of the above, Applicants respectfully submit that the rejection of the claims under 35 USC §103(a) as unpatentable over Maruyama in view of Zingerman, Friend, Abstract, and Norling has been overcome and should be withdrawn.

Conclusion

It is submitted that the foregoing amendments and remarks place the case in condition for allowance. A notice to that effect is earnestly solicited.

In the event that all of the claims are not in condition for allowance, Applicants respectfully request for an interview with the Examiner before the preparation of the next Office Action.

Respectfully submitted,

By: /William E. McGowan/
William E. McGowan
(Attorney for Applicants)
Reg. No. 39,301

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2197